DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

#14

Food and Drug Administration
Rockville MD 20857

MAY 26 1992

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DEPUTY ASSISTANT COMMISSIONER FOR PATENTS

Re: SUPPRELIN
Docket No. 92E-0133

The Honorable Douglas B. Comer
Acting Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Comer:

This is in regard to the application for patent term extension for U.S. Patent No. 4,244,946, filed by The Salk Institute for Biological Studies, under 35 U.S.C. 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Supprelin®, the human drug product claimed by the patent.

The total length of the review period for Supprelin is 2,876 days. Of this time, 1,930 days occurred during the testing phase and 946 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: February 8, 1984.

   The applicant did not specify in its application for patent extension an effective date for the investigational new drug application (IND). FDA records indicate that the date the IND became effective was February 8, 1984.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: May 22, 1989.

   The applicant claims May 19, 1989, as the date the new drug application (NDA) for Supprelin (NDA 19-836) was filed. However, FDA records indicate that NDA 19-836 was submitted on May 22, 1989.

3. The date the application was approved: December 24, 1991.

FDA has verified the applicant's claim that NDA 19-836 was approved on December 24, 1991.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Douglas D. Busch, Esq.